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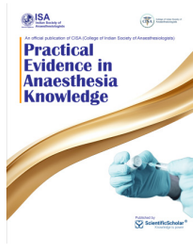

ORIGINAL ARTICLE

Comparison of analgesic efficacy of fentanyl and dexmedetomidine as adjuvant to intrathecal hyperbaric 0.75% ropivacaine for lower abdominal surgeries—A prospective double-blind randomised controlled study

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Received: 27 October 2024
Accepted: 26 December 2024
Published: 15 February 2025

DOI
10.25259/PEAK_13_2024

Quick Response Code:

ABSTRACT

Aims and Objectives: Various adjuvants are used to prolong intraoperative and postoperative analgesia after spinal anaesthesia. This study aimed to compare the onset and duration of sensory and motor block, haemodynamic effects, postoperative analgesia, and adverse effects of intrathecal dexmedetomidine or fentanyl as adjuvants with hyperbaric 0.75% ropivacaine.

Material and Methods: 100 American Society of Anesthesiologists I and II patients, between ages 20 and 60 years, undergoing elective lower abdominal surgeries were randomised to receive 3 ml of 0.75% hyperbaric ropivacaine with either 10 μg dexmedetomidine or 25 μg fentanyl as adjuvants intrathecally. Patients were assessed for the onset and duration of sensory and motor block, haemodynamic effects, two-segment sensory regression, duration of postoperative analgesia, postoperative pain scores, and any adverse effects.

Results: There was a significant difference ($p = 0.033$) between the two groups regarding the time for two-segment regression, with group D patients taking longer (144.88 ± 28.39 minutes) compared to group F (131.86 ± 31.61 minutes). The duration of analgesia was also significantly longer, $p < 0.001$, in group D (431.82 ± 85.38 minutes) than in group F (308.38 ± 66.92 minutes). Similarly, the duration of motor blockade was significantly longer in group D (360.86 ± 68 minutes) compared to group F (274.92 ± 70 minutes) ($p < 0.001$). A statistically significant difference in postoperative analgesic consumption between the two groups ($p = 0.002$), with patients in group F requiring more analgesics was observed.

Conclusion: 10 μg of dexmedetomidine provides a longer duration of anaesthesia and analgesia compared to 25 μg of fentanyl as an intrathecal adjuvant to hyperbaric 0.75% ropivacaine for abdominal surgeries.

Keywords: Anaesthesia, dexmedetomidine, fentanyl, ropivacaine, spinal

INTRODUCTION

Subarachnoid block is the most performed procedure for lower limb and lower abdominal surgeries due to its rapid onset, reliable motor and sensory blockade, relative safety, ease of administration, preservation of upper airway reflexes, cost-effectiveness, and low failure rates. To enhance the quality of the blockade, prolong the duration of analgesia, and minimise side effects, various adjuvants, such as opioids (morphine, fentanyl)[1,2], α-adrenergic agonists (dexmedetomidine, clonidine)[3,4], midazolam[5], and many other agents have been used.

Ropivacaine is an amide local anaesthetic, with properties similar to bupivacaine but with reduced cardiovascular toxicity on a milligram basis.[6] The sensory block produced by ropivacaine is superior and with lesser propensity for motor block. Due to higher clearance, the duration of action is also shorter. Ropivacaine preferentially blocks pain-transmitting nerve fibres (Aδ and C fibres) more effectively than those controlling motor function (Aβ fibres). Intrathecal isobaric ropivacaine alone produces a sensory block with a variable duration of analgesia. The conversion of ropivacaine to a hyperbaric form and the addition of adjuvants have been explored to enhance intraoperative anaesthesia quality and postoperative analgesia.[7]

Dexmedetomidine is a highly selective and potent α-2 adrenergic agonist (α2:α1 = 1,620:1), known for its sedative, hypnotic, and analgesic effects. It also has antinociceptive action for both somatic and visceral pain. When used as an adjunct with local anaesthetics for neuraxial blockade, dexmedetomidine is known to increase the duration of both motor and sensory blockade with minimal side effects. Fentanyl, when used intrathecally, selectively decreases the nociceptive afferent input from Aδ and C fibres without affecting dorsal root axons or somatosensory evoked potentials.[8]

Though both drugs are readily available in most operation theatres, fentanyl, being a potent opioid, may not be available in all healthcare centres. Dexmedetomidine is readily available, and its efficacy for intrathecal use has been proven.[3] Studies on intrathecal hyperbaric ropivacaine in combination with fentanyl or dexmedetomidine for postoperative analgesia following lower abdominal surgeries are limited. This study was undertaken to compare the safety, quality, and efficacy of 10 μg dexmedetomidine and 25 μg fentanyl as adjuvants with 3 ml of hyperbaric 0.75% ropivacaine given intrathecally. The primary objectives were to assess the duration of analgesia and the duration of motor blockade. Secondary objectives were to assess the cumulative analgesic consumption, pain score, and incidence of hypotension, bradycardia, and respiratory depression.

MATERIAL AND METHODS

After institutional ethical committee approval (RRMCH-IEC/95/2022), the study was registered in the Clinical Trials Registry-India (CTRI/2023/12/076598). Written informed consent was taken from 100 American Society of Anesthesiologists physical status I and II patients, 20–60 years of age, undergoing elective abdominal surgeries at a tertiary healthcare centre. It was a randomised prospective, double-blinded trial. We excluded those patients who refused to consent, reported an allergy to any of the study drugs, had any contraindications for spinal anaesthesia, were obese and weighed more than 100 kg, had a height more than 170 cm or less than 150 cm, were mentally retarded patients, pregnant and lactating women, had abnormalities of the spine, or with a basal heart rate <60/min.

Randomisation was done using computer-generated data and handed over to the investigators in sealed, opaque, sequentially numbered envelopes containing the allocated group. Group D patients received spinal anaesthesia with 3 ml of 0.75% hyperbaric ropivacaine with 10 μg dexmedetomidine (0.1 ml) mixed with 0.4 ml sterile normal saline. Group F patients received spinal anaesthesia with 3 ml of 0.75% hyperbaric ropivacaine with fentanyl (0.5ml).

Sample size was estimated by using the difference in mean time of sensory block in the isobaric ropivacaine 0.75% plus dexmedetomidine group and the isobaric ropivacaine 0.75% plus fentanyl group from the study by Ravipati et al. as 156.47 ± 33.78 seconds and 185.20 ± 35.17 seconds. Using these values at 95% confidence limit at 5% alpha error and 90% power, a sample size of 43 was obtained in each group. To compensate for 10% dropouts, 50 patients were included in each group.[9]

All patients were preoperatively assessed, and the procedure was explained in their own understandable language; a written and informed consent was taken. A visual analogue scale for pain assessment was explained to the patients. All patients received an alprazolam tablet at a dose of 0.5 mg and pantoprazole tablet at a dose of 40 mg the night before surgery. Patients were kept nil orally for a period of 8 hours preoperatively.

On reaching the operation theatre, the fasting status was confirmed. An 18-gauge intravenous (IV) cannula was secured to the non-dominant hand. Routine monitors, including non-invasive blood pressure (NIBP), electrocardiogram, and pulse oximetry, were connected. Patients were preloaded with Lactated Ringer's solution at the rate of 15 ml/kg. The anaesthetist conducting the case opened the sealed envelopes and prepared the spinal drug depending on the allocated group. Under aseptic conditions, spinal anaesthesia was performed at the level of the L3–L4 or L4–L5 interspace in the sitting position using a midline approach and a 25G Quincke spinal needle. The study drug was injected slowly over 10–15 seconds with the bevel of the needle pointing upwards, and the patients were made supine immediately. Assessment was done by another anaesthesiologist who was not involved in case management and was also blinded to the group allocation. Sensory levels were assessed by loss of sensation to pinprick using a 23G hypodermic needle on each dermatome at 1-minute intervals. Onset of sensory blockade was defined as the time taken for the block to reach the T10 dermatomal level. After that, the sensory level was checked every 2 minutes till the highest level stabilised for

four consecutive tests. Testing was then conducted every 15 minutes until the point of two-segment regression of the block. Onset of motor blockade was defined as the time taken for the block to attain Bromage grade 1.[10] Time taken for the block to achieve Bromage grade 3 was also noted.

Patients were monitored for heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SPO_2), and Ramsay sedation score at intermittent intervals of two minutes for the first 6 minutes, five minutes for the next 15 minutes, and every 30 minutes after that.[11] Hypotension was defined as a drop in SBP more than 30% below baseline value or less than 90 mmHg, and it was treated by bolus of 200 ml of intravenous fluids and, if required, incremental doses of 3 mg ephedrine if SBP remained below 90mm Hg. Bradycardia was defined as HR < 50 beats/min and was treated with Inj. atropine 0.6 mg IV. Any adverse events like nausea, vomiting, respiratory depression, shivering, and pruritus were noted. Patients were also assessed for regression of the block by two dermatomal segments, and the time was noted. After the surgery, patients were shifted to the post-anaesthesia care unit, where they were monitored until complete recovery of sensory and motor blockade.

Pain was assessed using the visual analogue scale (VAS) at 2, 4, 6, 8, 12, and 24 hours postoperatively. Time of request for rescue analgesia in the postoperative period was noted. Duration of analgesia was defined as the time from completion of injection of study drug to the time of first request for rescue analgesia. Patients with a VAS score of more than five received Inj. tramadol 1 mg/kg body weight. If pain persisted after 10 minutes of tramadol, patients received intravenous infusion of injection diclofenac 1 mg/kg body weight. Total analgesic consumption in 24 hours was noted. Motor recovery was assessed half hourly until Bromage grade 0 was achieved. Duration of motor blockade was defined as the time from onset of motor blockade to complete motor recovery to Bromage grade 0.

Data were entered into a Microsoft Excel data sheet and analysed using Statistical Package for the Social Sciences (SPSS) 22.0 (International Business Machines, Somers New York, United States of America) software. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as a test of significance for qualitative data. Continuous data were represented as mean and standard deviation. Normality of the continuous data was tested by the Kolmogorov–Smirnov test and the Shapiro–Wilk test. An independent t-test was used as a test of significance to identify the mean difference between two quantitative variables. Mann Whitney U-test was used for nonparametric data between the two groups. p-value < 0.05 was considered statistically significant.

Table 1: Demographic details of study population

	Group F (n = 50)	Group D (n = 50)	p-value
Age (in years) (Mean ± SD)	41.90 ± 13.379	41.02 ± 15.133	0.759
Gender (M: F)	27: 23	32: 18	0.309
ASA Grade (1: 2)	23: 27	23: 27	1.000
Height (in cm) (Mean ± SD)	159.00 ± 5.35	161.76 ± 7.03	0.03
Duration of surgery (in minutes) (Mean ± SD)	151.6 ± 12.29	147.7 ± 13.16	0.1195
Type of surgery			
• Inguinal hernia	27	28	>0.05
• Umbilical hernia	3	4	
• Incisional hernia	10	6	
• Abdominal hysterectomy	10	12	

ASA: American Society of Anesthesiologists; SD: Standard deviation; Group F: Patients receiving fentanyl; Group D: Patients receiving dexmedetomidine

Table 2: Comparison of Time for T10 level, Time for highest level and Bromage score distribution between the two groups

		Group F	Group D	p-value
Time for T10 level (min) (Mean ± SD)		3.62 ± 1.783	4.02 ± 1.953	0.288
Time for highest level (min) (Mean ± SD)		10.98 ± 3.62	11.24 ± 3.29	0.708
Bromage Score	1 (min) (Mean ± SD)	2.24 ± 1.22	1.92 ± 0.88	0.136
	3 (min) (Mean ± SD)	3.78 ± 1.74	3.82 ± 1.67	0.907

Group F: Patients receiving fentanyl; Group D: Patients receiving dexmedetomidine; SD: Standard deviation

RESULTS

143 patients were assessed for eligibility by continuous sampling. 35 patients did not fulfil the inclusion criteria. Eight patients refused to consent to the study. 100 patients therefore completed the study [Figure 1]. All patients were comparable regarding demographics [Table 1]. Even though there was a statistically significant difference in terms of height, it was clinically not significant [Table 1].

There was no significant difference between group F and group D regarding the onset of sensory (p = 0.288) and motor block (p = 0.136). The time taken to achieve the highest level was also not different between the two groups (p = 0.708) [Table 2]. Maximum number of patients (n = 92) achieved

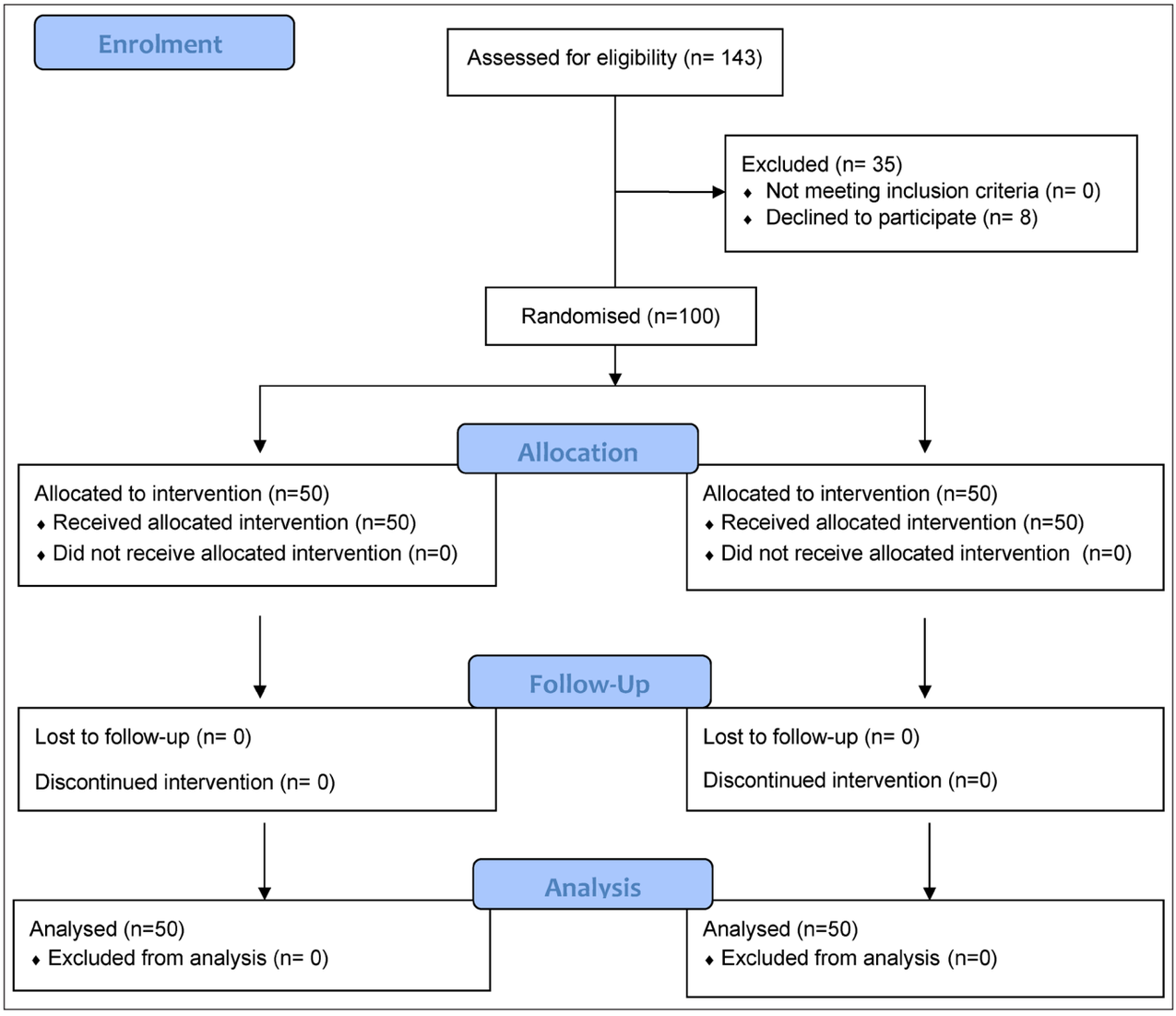

Figure 1: Consolidated Standards of Reporting Trials flow diagram

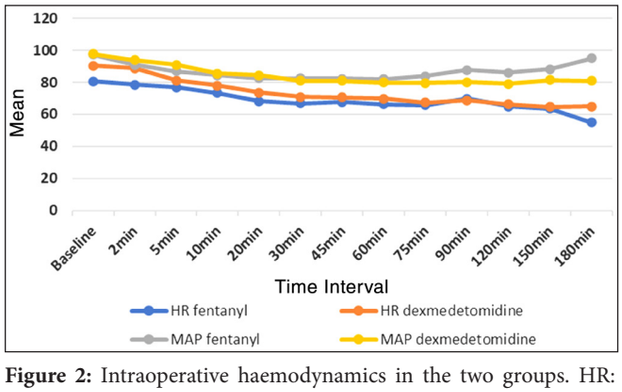

Figure 2: Intraoperative haemodynamics in the two groups. HR: heart rate; MAP: mean arterial pressure

T6 level of sensory blockade. Four patients achieved T4 level, and four patients achieved T5 level.

There was no significant difference between group F and group D regarding HR, SBP, DBP, and MAP throughout the study [Figure 2]. Patients in group F had a sedation score of 2, whereas many patients in group D showed a median Ramsay sedation score of 3. This was statistically significant [Figure 3].

There was a significant difference between the two groups regarding time for two-segment regression ($p = 0.033$), with group D patients taking longer time (144.88 ± 28.39 minutes) for two-segment regression than group F (131.86 ± 31.61 minutes). The duration of analgesia was also significantly

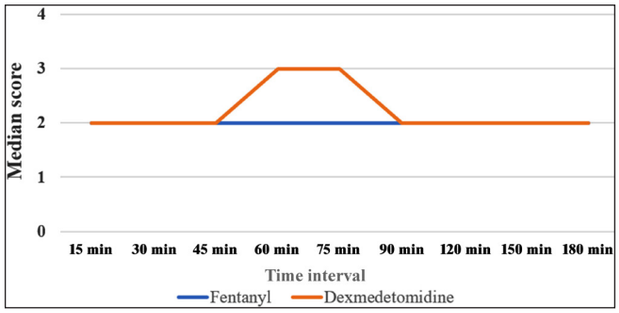

Figure 3: Median Ramsay Sedation Scale scores in the two groups at different time periods

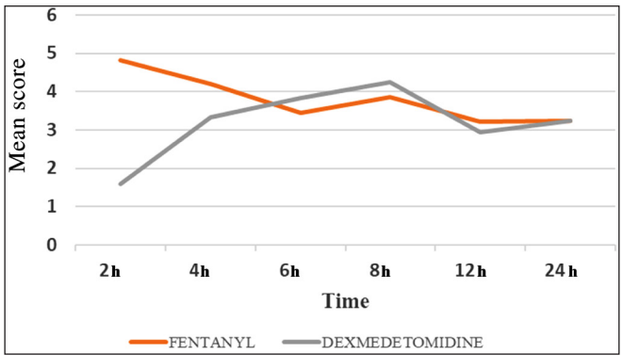

Figure 4: Visual Analogue Scale Score in the two groups at different periods of follow-up

longer in group D (431.82 ± 85.38 minutes) compared to group F (308.38 ± 66.92 minutes) ($p < 0.001$). The duration of motor blockade was also significantly longer in group D (360.86 ± 68.35 minutes) compared to group F (274.92 ± 70.19 minutes) ($p < 0.001$).

There was a significant difference regarding VAS scores between the two groups during the first 2 hours ($p < 0.001$) and at 4 hours ($p = 0.006$). VAS score at 6th, 8th, 12th, and 24th hours did not show any statistically significant difference [Figure 4].

There was a statistically significant difference between the two groups regarding postoperative analgesic consumption. ($p = 0.002$). Patients in group F required more doses of analgesics. No major complication requiring interventions was noted in any patient in either group.

DISCUSSION

In this study we assessed the efficacy of intrathecal dexmedetomidine and fentanyl added to hyperbaric ropivacaine in abdominal surgeries for prolonging the duration of analgesia and motor blockade. Intrathecal ropivacaine has been shown to produce local anaesthesia with equipotent sensory block but a shorter duration of motor block than intrathecal bupivacaine.[12,13] The current study showed that an adjunct like dexmedetomidine in a dose of 10 µg significantly prolongs the duration of analgesia and motor blockade by ropivacaine; besides, it provides appropriate sedation and decreased postoperative pain. Also, hyperbaric ropivacaine with dexmedetomidine 10 µg provides prolonged analgesia and motor blockade compared to adding fentanyl.

Gupta et al.[14] and Mowar et al.[15] in their study, found that 10 µg dexmedetomidine prolongs the duration of analgesia and motor blockade without causing any major haemodynamic impairment. So, we selected a 10 µg dose of dexmedetomidine for intrathecal administration to get maximum duration of analgesia without any adverse effects. Intrathecal fentanyl, when added to local anaesthetics, reduces visceral and somatic pain, as proved in many studies.[16] A dose of 25 µg is a widely used, safe intrathecal dose for adults. So, we selected this dose of fentanyl.

We planned to use commercially available ropivacaine heavy to maintain the sterility and ease of administration. There are limited studies in the literature using intrathecal hyperbaric ropivacaine. So, we planned this study to know the efficacy of hyperbaric ropivacaine when used with adjuvants like dexmedetomidine and fentanyl for prolonged motor blockade and analgesia.

There was no significant difference between intrathecal dexmedetomidine and fentanyl with regard to the onset of analgesia and motor blockade and the time required to achieve the highest level of sensory blockade [Table 2]. Our study results correlate with that of Mahendru et al.,[17] who also did not find any difference regarding the onset of sensory and motor blockade when dexmedetomidine, fentanyl, and clonidine were added to bupivacaine for patients undergoing lower limb surgeries. Several authors have reported no significant difference in the onset time of sensory and motor block with the addition of intrathecal dexmedetomidine or other adjuvants to local anaesthetics.[18]

Overall, all patients achieved an adequate surgical level of anaesthesia of T6. This may be due to the use of larger volume (3.5 ml) and hyperbaric ropivacaine as suggested by Dwivedi et al. in their study.[19] They evaluated plain and hyperbaric ropivacaine in patients undergoing lower abdominal surgeries under spinal anaesthesia. They found that the use of hyperbaric ropivacaine enhances the onset and reliability of blockade with a long duration of block for surgery. They opined that plain solutions are less reliable for surgeries above T10 dermatomal level. However, unlike their study, motor blockade was prolonged in our study, which may be due to the additives.

There was no significant difference between group F and group D regarding changes in HR, SBP, DBP, MAP, and SPO_2 [Figure 2]. MAP remained above 70 mmHg in all patients in both groups throughout the study. This may be due to the preloading. None of the patients experienced any episodes of desaturation. SPO_2 remained >97% in all the patients. None of the patients had bradycardia in our study. Our study results are similar to the study done by Gupta et al.[14] who also did not have any episodes of bradycardia or hypotension even with intrathecal dexmedetomidine of 10 μg. Studies involving the use of intrathecal 25 μg fentanyl also have not reported any haemodynamic impairments.[7]

Many patients in group D in the present study had Ramsay score of 3, which was statistically significant [Figure 3]. However, Ramsay score of 3 indicates comfortably sedated patients responding to verbal commands without any respiratory depression. This much sedation in the perioperative period is desirable. Our findings are similar to that of Gupta et al.[14] study. They compared different doses of intrathecal dexmedetomidine and found that the patients who received 10 μg dexmedetomidine were easily arousable to verbal commands.

Similar to the findings of Shashikala TK et al.,[7] in our study, patients in group D had a long time for two-segment regression and duration of analgesia compared to group F. With regard to motor blockade, our study results correlated with that of Gupta et al.[14] who also found prolonged duration of motor blockade (365 ± 26.52) minutes with intrathecal dexmedetomidine 10 μg. Thus intrathecal dexmedetomidine may prolong the duration of motor blockade by ropivacaine similar to that of bupivacaine.

With regard to pain scores as assessed by VAS, patients in group D had lower scores compared to group F patients during the 2nd hour and 4th hour postoperatively which was statistically significant. However, VAS scoring at the 6th, 8th, 12th, and 24th hours did not show any statistically significant difference. This may be due to the rescue analgesia that the patients received once VAS scoring was >4 [Figure 4]. This lower VAS score in group D resulted in delayed requirement of rescue analgesia, leading to overall less requirement of total analgesics in the 24-hour postoperative period ($p = 0.002$). This reduction in the requirement of postoperative analgesics with the use of intrathecal dexmedetomidine is documented in many studies.[7]

There is limited data in the literature regarding the use of hyperbaric ropivacaine for abdominal surgeries. Most of the studies have compared isobaric ropivacaine with additives. Also, many studies have compared dexmedetomidine with fentanyl when added to intrathecal bupivacaine. All these studies have concluded that intrathecal dexmedetomidine is a better alternative to fentanyl.[17] Our study results correlate with those of Shashikala et al.[7] who found that hyperbaric ropivacaine with additives such as dexmedetomidine and fentanyl hastens the onset and prolongs the postoperative analgesia with minimal haemodynamic and other side effects.

In our study, we did not find much difference in the onset of sensory and motor blockade or the time for achieving the highest level of blockade between group D and group F. However, patients in group D had a prolonged duration of analgesia and motor blockade and a lesser incidence of adverse effects compared to group F patients. This prolonged duration of motor blockade may be due to the higher volume used in our study (3.5 ml) and due to dexmedetomidine. This efficacy of dexmedetomidine 10 μg in prolonging the duration of analgesia and motor blockade and reducing the rescue analgesic requirement in the postanaesthesia care unit has been documented by Gupta et al.[14] A prolonged motor blockade may delay ambulation, but it will provide a longer duration of anaesthesia if the surgical procedure is prolonged, especially in abdominal surgeries, making it a very useful adjunct to local anaesthetics.

Our study had a few limitations. Inclusion of a third control group receiving 0.75% hyperbaric ropivacaine as a sole agent would have allowed the pharmacodynamic comparison of the addition of adjuvants to the local anaesthetic.

CONCLUSION

10 μg of intrathecal dexmedetomidine provides a longer duration of anaesthesia and analgesia compared to 25 μg of fentanyl as an adjuvant to hyperbaric 0.75% ropivacaine for abdominal surgeries.

Declaration of Patient Consent: The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Prasad RS, Hungund A, Shirolkar DV. Comparison of analgesic efficacy of fentanyl and dexmedetomidine as adjuvant to intrathecal hyperbaric 0.75% ropivacaine for lower abdominal surgeries—A prospective double-blind randomised controlled study. Pract Evid Anaesth Knowl. 2025;1:19–25. doi: 10.25259/PEAK_13_2024